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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,598	09/20/1999	MASAHIKO MIHARA	350292000800	4167

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EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/381,598	MIHARA, MASAHIKO	
	Examiner	**Art Unit**	
	Joseph F Murphy	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *14-22 and 33-38*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The reply filed 9/15/2003 does not overcome the rejection of claims 14-22 and 33-38 under 35 USC 103 as being unpatentable over Gijbels et al (1995) in view of Vink et al. (1990), and further in view of U.S. Patent No. 5,605,930 (Samid). Applicant argues that the previous Office Action was improperly made final because the '930 patent was newly cited. However, as pointed out in the previous Office Action, Applicant's amendment necessitated the new ground(s) of rejection presented in the Office action, thus the action was properly made final.

Applicant argues that there is no teaching or suggestion to combine the references, and that that there must be some suggestion in the cited documents that an antibody to the IL-6 receptor could be used in the claimed methods. However, the Gijbels reference teaches a method of protecting against development of EAE by the administration of a protein with anti-IL-6 activity, in this case an anti-IL 6 antibody. The Vink reference teaches the protective effects of both anti-IL-6 and anti-IL-6 receptor antibodies, both of which block IL-activity. As taught in the Gijbels reference, anti-IL-6 activity has protective benefits in the EAE model of MS. Applicant further argues tha there is no conclusion in the Gijbels reference that neutralizing IL-6 with an antibody could be used to treat a T-cell mediated disease. However, the Gijbels reference further teaches that the protective effect of anti-IL-6 therapy in EAE would have therapeutic effects in MS (Gibels at 804, column 1).

Applicant additionally argues that Vink fails to indicate that an antibody to IL-6 can be exchanged for an antibody to the IL-6 receptor. However, the Gijbels reference uses antibodies with anti-IL-6 activity in the art recognized MS mode, EAE, and further teaches that anti-IL-6 activity has protective benefits in the EAE model of MS (Gijbels at 804, column 1). The Vink reference teaches the efficacy of blocking IL-6 activity with either anti-IL-6 antibodies, or antibodies to IL-6 receptor.

Applicant further argues that the '930n patent fails to teach that IL-6 expression is involved in T-cell mediated diseases. However, the '930 patent discloses the central role that IL-6 plays in inflammatory processes, it would be an expected property of the method of administration of anti-IL-6 receptor antibodies to treat MS, that this method of administration would treat other autoimmune and inflammatory processes, such as uveitis, thyroiditis, dermatitis and hypersensitivity.

Applicant further argues that there was no expectation of success, however, the Gijbels reference teaches that anti-IL-6 activity has protective benefits in the EAE model of MS, and the Vink reference teaches the efficacy of the use of antibodies to IL-6 receptor..

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